

## VALIDATION PROTOCOL

### Dynamiker Aspergillus Galactomannan Assay

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**Purpose:** assessment and performance of the DNK Aspergillus Galactomannan kit and the Platelia Aspergillus EIA in serum from adult neutropenic oncohaematological patients with a highly expect prevalence of invasive aspergillosis.

Clinical data and sera will be collect prospectively and patients classified according to the European Organization for Research and Treatment of Cancer (EORTC)/Mycoses Study Group (MSG) 2008 guidelines.

#### Results:

Clinical testing to evaluate the sensitivity, specificity and predictive value of the DNK Aspergillus Galactomannan was conducted on adult neutropenic oncohaematological patients using a total of 58 patients from the following populations:

- Patients without signs of Invasive Aspergillosis (control patients)
- Patients with probable Invasive Aspergillosis
- Patients with proven Invasive Aspergillosis

#### 1. Sensitivity

- Proven Aspergillosis: was 81.8% (95% Confidence Interval 52.3 – 94.9%)
- Probable Aspergillosis: was 77.8% (95% Confidence Interval 54.8 – 91.0%)
- Combined Proven and Probable Aspergillosis: 79.3% (95% Confidence Interval 61.6 – 90.2%)

#### 2. Specificity: the test showed 80.5%

#### 3. Reproducibility: the results from the standards and controls were generally reproducible between days. Some variability in results was seen with the standard “a” and “b”.

**Conclusions:**

- The performance characteristics of Platelia Aspergillus EIA and DNK Aspergillus Galactomannan kit were similar for these tests.
- Prospective studies are needed to determine more value of the new assay.